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REVIEW

The Role of Superficial Venous Surgery in the Management of Venous Ulcers: A Systematic Review

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Abstract *Background:* The complicated natural history of venous ulcers requires the continued development and improvement of treatments to ensure the most effective management. Compression therapy or surgical correction of superficial venous incompetence (SVI) are currently the main methods employed for the treatment for venous ulceration (VU). This review compares and summates the healing and recurrence rates for each treatment modality used over the last thirty years.
Methods: Sixty-one articles investigating compression and superficial venous surgical treatments were obtained from a systematic search of electronic databases (Medline, Embase, The Cochrane Library, and Google Scholar) and then an expanded reference list review. Patient demographics, CEAP classification, patterns of venous insufficiency, type of intervention, length of follow up, healing and recurrence rates for venous ulceration was assessed. Inadequate data in seven reports led to their exclusion. Recent randomised controlled trials (RCTs) specifically comparing superficial surgery to compression therapy were reviewed and data from non-randomised and/or 'small' clinical studies prior to 2000 underwent summation analysis.
Results: Five RCTs since 2000 demonstrate a similar healing rate of VU with surgery and conservative compression treatments, but a reduction in ulcer recurrence rate with surgery. The effect of deep venous incompetence (DVI) on the ulcer healing is unclear, but sub-group analysis of long-term data from the ESCHAR trial suggests that although surgery results in a less impressive reduction in ulcer recurrence in patients with DVI, these patients appear to still benefit from surgery due to the haemodynamic and clinical benefits that result. The RCTs also highlight that a significant proportion of VU patients are unsuitable for surgical treatment.

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Summation of data from earlier studies (before 2000), included twenty-one studies employing conservative compression alone resulted in an overall healing rate of 65% (range 34—95%) and ulcer recurrence of 33% (range 0—100%). In thirty-one studies investigating superficial venous surgery, the overall rate of ulcer healing was 81% (range 40—100%) with a post-operative recurrence rate of 15% (range 0—55%). The duration of follow up care in the surgical studies was approximately twice as long as in the conservative studies, which would lend to more reliable recurrence data.

Conclusions: Evidence from the current literature, would suggest that superficial venous surgery is associated with similar rates of ulcer healing to compression alone, but with less recurrence. The effects of post-operative compression and DVI on the efficacy of surgery are still unclear.

Introduction

Chronic venous ulcers represent a major burden to health care services affecting at least one percent of the population at a cost of over £400 million per year for their treatment.[1] Because of the substantial morbidity, financial and psychosocial cost it is important to identify the most effective means of treatment for venous ulceration. The progressive development and modification of treatments are essential to contest the natural history of prolonged ulceration and recurrence that makes venous ulceration extremely difficult to cure.

Superficial or deep venous incompetence allows high-pressure venous blood to gravitate to the ankle. Venous hypertension is thought to be the principal cause of venous ulceration, secondary to superficial and deep venous insufficiency,[2–4] obstruction to venous flow, and/or failure of the ''venous calf pump''.[5] Other associated factors include elevated ambulatory venous pressures, minor trauma, oedema, obesity, arthritis and neuropathies.[6,7] Pathophysiological abnormalities contribute to changes at a cellular level that result in venous ulceration, for which a number of hypotheses have been put forward.[7–11] Despite varying explanations for venous ulceration, it appears that correction of venous hypertension results in ulcer healing and lower recurrence.[12]

Compression therapy and surgical correction of superficial venous incompetence are the main methods currently employed for the treatment for venous ulceration. Graduated external compression to the lower extremity has resulted in accelerated healing of venous ulcers and has become the mainstay of treatment.[12–14] However, a recent review of conservative treatments suggested that all 'recognised' high compression-bandaging techniques were similar in efficacy, and success relied upon the correct application of the chosen system.[14] Compression bandaging therapy is thought to produce a decrease in ankle fluid, softening of the lipodermatosclerosis, decrease in venous volume, increase in deep venous velocity, blood shifts into central compartments, reduction in venous reflux, improvement of venous pumping, improvement in microcirculation and lymph drainage.[12] However, recurrence rates (after healing) with continued compression therapy are high, especially in those patients who are poorly compliant.[15,16] The high recurrence rate with compression therapy may be due to the continued presence of the underlying venous defect.

Surgical management aims to remove or correct the venous abnormalities in the superficial or deep venous systems of the leg. In the perfectly compliant patient (such as in the clinical trial scenario), conservative compression and superficial surgery treatments may achieve similar rates of venous ulcer healing. However, surgery by virtue of its ability to correct the underlying venous defect; may offer superior results in terms of ulcer recurrence and therefore long term treatment. The aim of this review of recent RCTs (post-2000) and summation analysis of earlier (pre-2000) non-randomised or 'small' studies was to compare healing and recurrence rates for conservative and superficial surgical therapies employed in studies over the last thirty years.

Materials and Methods

The following steps were performed in the production of this systematic review; formulation of a question, literature search, critical appraisal, paper selection, and statistical analysis and interpretation. We sought to assess whether healing and recurrence rates of venous ulceration differ for conservative and superficial surgical therapies employed in studies over the last thirty years.

Literature search and study retrieval

Reports of conservative compression treatment and superficial venous surgery for the management of venous ulceration were collected from a systematic electronic search of specialist databases (MEDLINE, Embase, The Cochrane Library, and Google Scholar) using MeSH terms and keyword searches and a secondary search of reference lists. Sixty-one studies were amassed, these consisted of five recent RCTs published since 2000 and 56 non-randomised or 'small' studies published before 2000.

Critical appraisal and paper selection

Study inclusion criteria required clear reporting of data for:

1. Absolute patient numbers with active venous ulceration (C-class 6 in the CEAP classification[17]) that healed with treatment.
2. Absolute patient numbers with healed venous ulceration (C-class 5 in the CEAP classification[17]) that recurred after treatment.
3. Individual data for patients receiving superficial surgical interventions.

Twenty-one studies investigating conservative therapy[18–34], twenty-eight surgical[35–62] and three studies comparing both treatment modalities[63–65] were included. In seven papers insufficient data led to their exclusion.[66–72] All studies excluded patients with dermal ulceration of non-venous origin.

Data analysis

The studies were analysed and data abstracted with regard to the patient demographics; CEAP classification; type of venous insufficiency, type of intervention, length of follow up, healing time, healing and recurrence rates for venous ulceration. We also collected data on risk factors associated with non-healing and ulcer recurrence.

Statistics

Statistical analysis incorporated the use of the SPSS statistical software version 14.0 (SPSS Inc. Headquarters, 233 S. Wacker Drive, 11th floor, Chicago, Illinois 60606) with P values of less than 0.05 considered significant. Non-parametric data are given as medians or percentages with ranges in brackets, parametric data are given as means with standard deviations in brackets.

Results

Review of recent randomised controlled trials comparing superficial venous surgery to conservative compression therapy of venous ulceration

Since 2000, there have been five RCTs[73–78] carried out to assess the efficacies of superficial venous surgery and conservative compression therapy with regard to the healing and recurrence of VU (C-class 6 in the CEAP classification). The results from four of these are summarised in Table 1 below,[73–76,78] the fifth study (USABLE trial) failed to recruit adequate numbers to achieve a meaningful result.[77] The ESCHAR trial and the van Gent *et al*. study were the largest studies with over a hundred patients or more in each arm.[75,76] The long-term data from the ESCHAR study demonstrated after 4 years an improved recurrence rate (31%) after surgery with compression, over compression therapy alone (56%) ($p < 0.01$), but no improvement in healing rate.[78] The van Gent *et al*. study primarily assessed sub-fascial endoscopic perforator surgery (SEPS) with saphenous surgery as an adjunct; in this study healing and recurrence rates were similar but ulcer free rates were statistically improved in favour of surgery.[75] Zamboni *et al*. demonstrated significantly improved healing and recurrence rates after 'minimally invasive surgical correction of reflux', however the numbers of patients in this study were small ($n = 46$).[74] Guest *et al*. investigated superficial venous surgery (including SEPS) combined with four-layer bandaging compression versus four-layer bandaging compression alone. This study with approximately forty patients in each treatment group, did not show a difference in healing rates for VU and recurrence rates were not assessed.[73]

The effects of deep venous incompetence (DVI) on healing and recurrence of ulcers after surgery are still unconfirmed despite of these randomised trials. Guest *et al*. found that the presence of DVI did not affect ulcer healing rates.[73] The subgroup analysis by venous reflux pattern showed no difference in healing rates in the ESCHAR trial.[76] In terms of recurrence after surgery or compression therapy; long-term results from the ESCHAR trial confirm that superficial venous surgery significantly lowers ulcer recurrence rates when compared to compression alone in patients with isolated superficial venous incompetence (SVI) and SVI with segmental deep reflux at four years.[78] Patients with both SVI and total DVI had lower recurrence at four years following surgery (32% vs 46%) but this was not significant ($p = 0.33$).[78] This long-term data also suggests that surgery results in more ulcer free time for all patients after three years than compression alone (78% vs 71%, $P = 0.007$).[78]

Although ulcer recurrence seems to be reduced by superficial venous surgery, the other important observation in these studies was the number of patients with VU who are actually not suitable for surgical intervention. In the ESCHAR trial 653 of 1418 patients assessed were unsuitable for surgery for a number of reasons.[76] These included arterial disease, the pattern of DVI, co-morbidity, incomplete imaging, unable to consent and ulcer malignancy. Similarly in the other studies, 130 of 206 patients were unsuitable for surgery[73] and in the USUABLE the low number of surgical candidates, approximately 180 from 759 patients interviewed caused the failure of the trial.[77]

Table 1 Results of recent RCTs comparing superficial venous surgery to compression therapy for treatment of venous ulcers

Study	Guest *et al*.[73]		Zamboni *et al*.[74]		ESCHAR[78]		Van Gent[75]	
Date published	2003		2003		2007		2006	
Treatment (Sx/Cx)	Sx	Cx	Sx	Cx	Sx	Cx	Sx	Cx
Number of legs	37	39	21	24	242	258	97	103
VU healed (%)	68	64	100*	96	93	89	83	73
VU recurrence (%)	N/a	N/a	9*	38	31*	56	22	23
Ulcer-free rate (%)	N/a	N/a	N/a	N/a	78*	71	72*	53
Follow-up period in months (healing & reccurrence)	6.5	6.5	36	36	36 &48	36 &48	29	26

Sx, superficial venous surgery; Cx, compression therapy without surgery; *, statistically significant result; N/a, not assessed.

Summation analysis of clinical studies prior to 2000

The summated results from the superficial surgical studies achieved better venous ulcer healing and recurrence rates than the overall rates for the conservative compression studies (Table 2, Fig. 1). The age ranges and sex ratios were similar in each group, however the greater duration of patient follow-up surveillance in the surgical studies would lend to more dependable data on ulcer recurrence. Eight articles reported durations for complete healing of venous ulcers, these details are displayed in Fig. 2. The mean healing times were only given in a small number of studies; four surgical[46,52,55,59] and four conservative,[22,24,25,29] the summation of mean values calculated a healing rate of 65 and 63 days respectively. However, the trend displayed in Fig. 2 suggested that surgically treated ulcers[41,43,46,52–55,59,64,65] may heal faster than with conservative therapy.[19,30,32,33]

Ulcer healing and recurrence rates from articles that employed a particular type of surgical intervention (saphenous and/or perforator) and with synchronous level III (40—50 mmHg) post-operative venous compression (bandaging or hosiery) were compared to summated data from conservative compression studies (Fig. 3). The superior results for saphenous surgery alone are taken from only four studies with a low number of limbs in each category, 221 limbs for 'healing' and 74 limbs for 'recurrences'. The use of level III (40—50 mmHg) compression after surgery did not notably improve healing and recurrence rates (Fig. 3). Interestingly, a direct comparison in one study showed no difference between surgery with post-operative compression and surgery alone or compression alone.[61]

A number of studies reported clinical factors that were found to be detrimental to the successful healing of venous ulcers. These include the presence of:

- Deep venous changes secondary to past episodes of deep vein thrombosis[39,41,44,47,49,50,59]
- Deep venous incompetence,[49]
- Multiple previous episodes of venous ulceration,[79]
- Large ulcer area,[55,79,80]
- Bilateral ulceration.[41]

Some studies gave individualised data for those patients with concomitant deep venous insufficiency or post-phlebitic syndrome. Nachbur[49] reported a 59% compared to 100% healing rate for limbs with and without DVI or post-thrombotic syndrome (PTS) respectively. Nash[50] achieved a 100% healing in patients with SVI alone, however 41 % of ulcers either failed to heal or recurred in individuals with popliteal vein incompetence.

Table 2 Summation of data for conservative and surgical studies prior to 2000

Venous Ulcer:	All Surgery	Compression Alone
Number of studies (number of limbs)	31 (1579)	21 (2500)
Percentage healed (range)	81% (40—100)	65% (34—95)
Percentage recurred (range)	15% (0—55)	33% (0—100)
Average maximum follow up (range)	5 years (0.6—13)	2.1 years (0.3—13)
Sex ratio - percentage male (range)	54% (26—100)	51% (31—100)

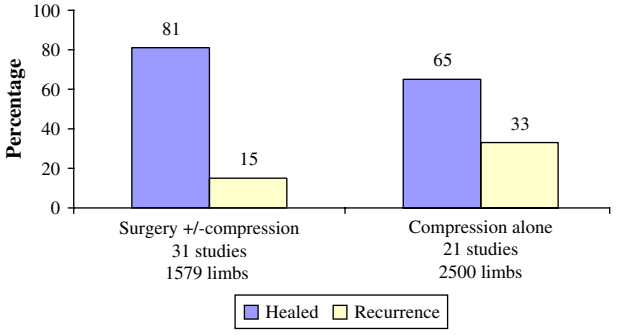

Figure 1 Overall Results for Surgery and Conservative Compression Therapies Summated from Studies Prior to 2000. Healing rates are based on active ulcers which have healed (C-class 6 to C-class 5). Recurrence rates are based on limbs with C-class 6 that healed and then recurred or C-class 5 limbs which progressed to C-class 6 during the observation period.

Discussion

The recent randomised trial data taken from five studies demonstrated a reduced rate of venous ulcer recurrence after surgery (with compression), but no improvement in healing rate when compared to conservative compression therapy alone.

Summation data from the earlier literature (before 2000) indicated that surgical correction with or without postoperative compression would seem to be associated with greater and earlier absolute healing and less recurrence of venous ulcers. However, this data — unlike the randomised data - was not homogeneous and a number of conflicting variables have been recognised that may

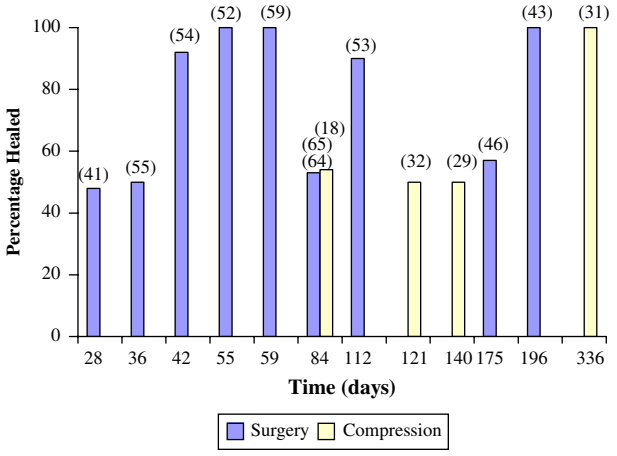

Figure 2 Ulcer healing times for surgery and conservative therapies.

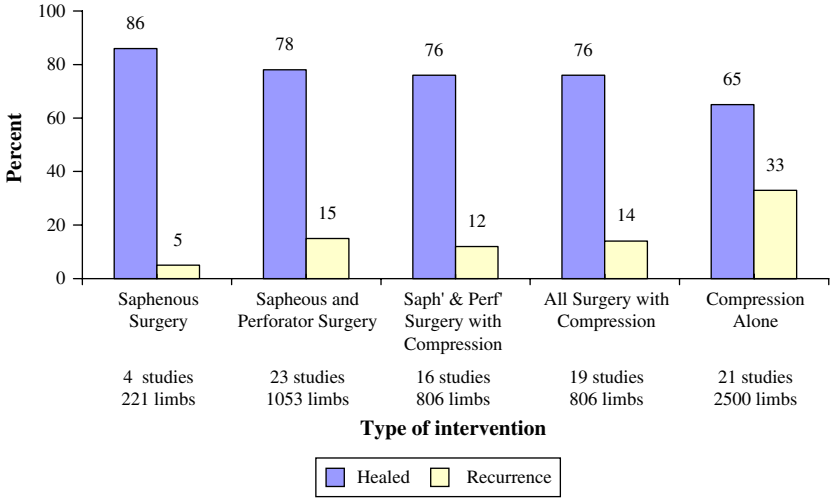

Figure 3 The Healing and Recurrence Rates for Surgery Subtypes and Compression Therapies prior to 2000. Healing rates are based on active ulcers which have healed (C-class 6 to C-class 5). Recurrence rates are based on limbs with C-class 6 that healed and then recurred or C-class 5 limbs which progressed to C-class 6 during the observation period.

influence the certainty of any possible surgical advantage. The observed higher healing and lower recurrence rates in the surgically treated patients may be due to selection bias. Those being chosen for surgery tend to be 'fitter' patients, who may have a better healing ability than frail patients deemed unfit for surgery.[65] Conversely, it can be argued that many surgical patients have previously failed the best medical treatments and surgery is the last available treatment option for a 'difficult' ulcer. Sixteen studies[35–39,41,46,47,50–54,57,58,60] reported that many of their patients had undergone and failed a trial of best medical treatment; in five of these studies all of their patients had previously failed compression therapy.[35,39,41,50,60]

In order to justify venous surgery, it must offer considerable benefits over compression therapy alone in terms of healing rate, recurrence, pain relief, cost and quality of life to outweigh the potential risks of anaesthesia and invasive intervention. Some studies have sought to lessen the risks by performing superficial venous surgery under local and/or regional anaesthesia.[85,81] The question arises on the management of the 'resistant' VU that has failed to heal despite maximal compression therapy and surgical correction of venous incompetence? If compression and superficial venous surgery have not managed to heal the VU after 6–12 months post-surgery, then skin grafting may be beneficial in this situation in combination with compression therapy.[82]

There have been countless debates over the influence that DVI plays on healing and recurrence of venous ulcers. A number of authors have reported the reduced healing ability of patients with venous ulcers in the presence of deep venous insufficiency.[18,49] In patients with DVI, Browse[9] and Bradbury[37] found poor healing and high recurrence rates in venous ulcers treated by superficial and perforator vein surgery. Sottiurai[60] demonstrated that superficial surgery and post-operative compression therapy was less effective than combined superficial surgery, deep surgery and compression therapy in healing recurrent venous ulcers (refractory to conservative treatments) in the presence of deep venous incompetence. Furthermore, some studies have reported improved healing results after superficial surgery when the deep veins are competent.[49,58]

On the other hand, Gloviczki *et al.*[44] established that the presence of deep vein incompetence does not affect healing in patients treated with superficial and perforator surgery, however detrimental effects were found in the presence of PTS and venous occlusive disease. Rhodes *et al.*[55] found that the presence of DVI did not affect clinical outcome although patients with PTS did not show haemodynamic improvements after surgery. In addition, studies have noted the reversal of DVI after surgical correction of superficial venous insufficiency, which supports the argument against DVI having a detrimental influence after superficial venous surgery.[42,56,76,83] Studies have also found superficial surgery caused the normalisation of dorsal vein pressures[84] and the improvement of calf pump function.[52,70,72] Sub-group analysis of the long-term data from the ESCHAR trial suggests that although superficial venous surgery results in a less impressive reduction in ulcer recurrence in patients with DVI, these patients appear to still benefit from surgery due to the haemodynamic and clinical benefits that result.[78]

The contradictory evidence for the contribution of DVI towards healing and recurrence of venous ulcers, together with the multiplicity of reporting by studies with varied treatment techniques, populations, postoperative management and lengths of follow up highlight the drawbacks of the evidence prior to 2000. Additionally, these studies did not assesses the presence of outflow obstruction comprehensively, which, like DVI, may influence VU healing and recurrence rates. At this time, there was an urgent need for randomised control trials to access the role of superficial venous surgery in the treatment of VU, the subsequent trials showed improvements only in terms of ulcer recurrence. Unfortunately, the recent RCTs do not provide significant further evidence for the effects of DVI on ulcer healing and recurrence; further studies are required. But, common ground does exist between authors on the unfavourable effects on the treatment of VU in the presence of

PTS and venous occlusive disease; a previous deep vein thrombosis or proven PTS has been shown to be an adverse prognostic factor in the healing of venous ulcers.[39,41,44,47,49,50,55,59,85]

In summary, the principal cause of venous ulcers in up to fifty percent of cases appears to be related to simple underlying varicose veins,[86,87] and therefore potential benefit should theoretically be gained from superficial venous surgery alone.[88] This seems to be true only for recurrence but not for healing rate (level I evidence)[75,76,78] The early data published prior to 2000 suggested that healing and recurrence may be enhanced by superficial venous surgery but recent RCTs have only shown recurrence to be improved. A number of other factors may affect the role of surgery in patients with venous ulceration and the number of potential candidates suitable for venous surgery from the population with venous ulceration ranges from less than half to around a third.[73,76,77] The success of conservative compression therapy is heavily reliant on patients' compliance which is usually better in the trial setting.

Conclusion

Evidence from the current literature, would suggest that superficial venous surgery is associated with similar rates of ulcer healing to compression alone, but with less recurrence. The effects of post-operative compression and DVI on the efficacy of surgery are still unclear.

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None.

Ethical Approval

Not required.

Competing Interests

None.

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